



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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HFI-55(URGENT)  
Public Health Service  
MARION

Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3461 x122  
FAX: (410) 962-2219

July 28, 1999

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

David T. Krausman, Ph.D.  
Vice President and Chief Executive Officer  
Individual Monitoring Systems, Inc.  
1055 Taylor Avenue  
Baltimore, Maryland 21286

Dear Dr. Krausman:

On May 25-26, 1999, Food and Drug Administration (FDA) Investigator Alan C. Gion collected information that revealed serious violations involving products manufactured and distributed by your firm, specifically the ActiTrac Activity Monitor, Display and Analysis Software, and the Sleep Scoring Program.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are defined as medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Review of the labeling for the ActiTrac and accessory devices revealed that they are labeled and promoted for use in recording and documenting physiological conditions associated with the assessment of sleep. These claims represent or suggest that the ActiTrac and related devices are used to monitor or provide physiological data to evaluate a patient's medical condition (i.e., insomnia) for diagnosis and treatment of a sleep disorder. As such, the intended use of the products includes the diagnosis of a disease or other condition and use in the cure, mitigation, treatment, or prevention of disease. Therefore, the ActiTrac Activity Monitor, Display and Analysis Software, and Sleep Scoring Program are considered devices as defined by Section 201(h) of the Act.

Our records show that you did not obtain marketing clearance before you began offering your products for sale. Because you do not have marketing clearance from FDA, your products are in violation of the Act. That is, your products are deemed misbranded under Section 502(o) and adulterated under Section 501(f)(1)(B). Your products are misbranded because you did not submit a premarket notification to FDA, as required by Section 510(k) of the Act, showing that your devices are substantially equivalent to other devices that are legally marketed. Until you

submit a premarket notification and receive notice from FDA clearing your devices for commercial distribution, they are also deemed adulterated under Section 501(f)(1)(B). This is because devices that FDA has not cleared for marketing automatically require an approved Premarket Application (PMA).

These are serious violations of the law that may result in FDA taking regulatory action without further notice. These actions include, but are not limited to, seizure of your products, injunction against further marketing of the products, or assessing civil money penalties. Also, other Federal agencies are informed about Warning Letters so that they may consider this information when awarding government contracts.

It is necessary that you take immediate action on this matter. Please notify this office in writing, within fifteen (15) working days from the date you receive this letter, of the specific steps you are taking to correct these violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, please state the reason for the delay and the time within which the corrections will be completed.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your devices and does not necessarily address other obligations you have under the law. You may obtain specific information about submitting a premarket notification and general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

Your reply should be sent to the Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122 if you have questions about the content of this letter.

Sincerely,

A handwritten signature in cursive script, reading "Carl E. Draper".

Carl E. Draper

Acting Director, Baltimore District